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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No.: 10/569,076 First Named Applicant: Wolfgang E. Berdel

Examiner: Allen, Marianne P Art Unit: 1647 Status of Application: Pending

Tentative Participants:

(1) Wolfgang E. Berdel, Albrecht Menges (by telephone) (2) Curtis R. Altmann

(3) Kristan L. Lansbery (4) Marianne P. Allen

Proposed Date of Interview: June 24, 2009 **Proposed Time:** 1:00 PM **AM/PM**

Type of Interview Requested:

(1) ☑ Telephonic (2) ☑ Personal (3) ☐ Video Conference

Exhibit To Be Shown or Demonstrated: ☐ YES ☑ NO

If yes, provide brief description:

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) Rej. (112, 1st. enab)	19-20, 24, 26-37, 39, 41	n/a	☐	☐	☐
(2) Rej. (112, 1st w.d.)	19-21, 24, 26-27, 29, 31-37, 39, 41	n/a	☐	☐	☐
(3) Rej. (112, 2nd)	20-21, 39, 41	n/a	☐	☐	☐
(4)			☐	☐	☐

☐ Continuation Sheet Attached

Brief Description of Argument to be Presented:

The claimed invention complies with the written description and enablement requirments under 35 U.S.C. § 112 first paragraph. The claimed invention complies with the definiteness requirements under 35 U.S.C. § 112 second paragraph. Inventor to discuss scientific papers cited in the Office Action. Further discuss proposed amendments (attached).

An interview was conducted on the above-identified application on _____

NOTE: This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

Kristan L. Lansbery
Applicant/Applicant's Representative Signature

Kristan L. Lansbery
Typed/Printed Name of Applicant or Representative

53,183
Registration Number, if applicable

Examiner/SPE Signature

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

US Appln. No. 10/569,076
Draft Claims for Examiner's Consideration

~~1~~-18. (Cancelled)

19. (Previously Presented) A fusion polypeptide, comprising
a. a peptide of 3 to 30 amino acids comprising the amino acid sequence RGD or NGR, wherein said peptide selectively binds said fusion polypeptide to a tumor vessel endothelial cell; and
b. a tissue factor or a fragment thereof that activates blood clotting when said fusion polypeptide selectively binds to said tumor vessel endothelial cell, ~~wherein said tissue factor or said fragment thereof comprises an amino acid sequence selected from the group consisting of a sequence having at least 95% homology to SEQ ID NO: 1, a sequence having at least 95% homology to SEQ ID NO: 2, a sequence having at least 95% homology to amino acid positions 11 - 218 of SEQ ID NO: 2, a sequence having at least 95% homology to amino acid positions 1 - 210 of SEQ ID NO: 2, and a sequence having at least 95% homology to amino acid positions 1 - 214 of SEQ ID NO: 2,~~ and said peptide of 3 to 30 amino acids is coupled to the C-terminus of said tissue factor or said fragment thereof.

20. (Currently Amended) The fusion polypeptide according to claim 19, wherein said coupling comprises ~~further comprising~~ a linker having up to 15 amino acids ~~linked~~ between [[to]]the C-terminus of said tissue factor or said fragment thereof and the N-terminus of said peptide of 3 to 30 amino acids.

21. (Currently Amended) The fusion polypeptide according to claim 19, wherein said coupling ~~said peptide is coupled directly to said tissue factor or said fragment thereof~~ is direct.

22 - 23. (Canceled)

24. (Currently Amended) The fusion polypeptide according to claim 19, wherein said peptide of 3 to 30 amino acids ~~has a linear structure or a~~is cyclic ~~structure~~.

25. (Canceled)

26. (Previously Presented) The fusion polypeptide according to claim 19, wherein said peptide of 3 to 30 amino acids is selected from the group consisting of GRGDSP (SEQ ID NO: 33) and GNGRAHA (SEQ ID NO: 34).

27. (Previously Presented) The fusion polypeptide according to claim 19, wherein said peptide of 3 to 30 amino acids is selected from the group consisting of GCNGRCG (SEQ ID NO:36), GCNGRCVSGCAGRC (SEQ ID NO:37), GCVLNGRMEC (SEQ ID NO:38), and GALNGRSHAG (SEQ ID NO:35).

28. (Previously Presented) The fusion polypeptide according to claim 19, wherein said fusion polypeptide has the sequence selected from the group consisting of SEQ ID NOs: 3-8.

29. (Previously Presented) A nucleic acid molecule encoding a fusion polypeptide according to claim 19.

30. (Previously Presented) The nucleic acid molecule according to claim 29, wherein said fusion polypeptide has the sequence selected from the group consisting of SEQ ID NOs: 10-15.

31. (Previously Presented) A vector comprising a nucleic acid molecule according to claim 29.

32. (Previously Presented) A cell for the expression and recombinant production of a fusion polypeptide comprising a nucleic acid molecule according to claim 29.

33. (Previously Presented) A cell for the expression and recombinant production of a fusion polypeptide comprising a vector according to claim 31.

34. (Previously Presented) A pharmaceutical composition comprising a fusion polypeptide according to claim 19 and a pharmaceutical carrier, excipient, adjuvant, or combination thereof.

35. (Previously Presented) A pharmaceutical composition comprising a nucleic acid molecule according to claim 29 and a pharmaceutical carrier, excipient, adjuvant, or combination thereof.

36. (Previously Presented) A pharmaceutical composition comprising a vector according to claim 31 and a pharmaceutical carrier, excipient, adjuvant, or combination thereof.

37. (Previously Presented) A pharmaceutical composition comprising a cell according to claim 32, and a pharmaceutical carrier, excipient, adjuvant, or combination thereof.

38. (Canceled)

39. (Currently Amended) A method of treating a patient with a vascularized neoplastic disease using a pharmaceutical composition according to claim 34, comprising administering said pharmaceutical composition to said patient, wherein said vascularized neoplastic disease is selected from the group consisting of lung carcinomas, sarcomas, breast cancer, malignant melanomas, prostate cancers and other urogenital tumors, endocrine-active tumors, and fibrosarcoma and said treating induces thrombosis in tumor vessels.

40. (Canceled)

41. (Currently Amended) The method according to claim 39, wherein said administering is selected from the group consisting of intravenous[[ly]], subcutaneous[[ly]], oral[[ly]], and intraperitoneal administration, wherein said oral administration is of a gastrointestinal cleavage resistant formulation.

42. (New) The fusion polypeptide of Claim 19, wherein said tissue factor comprises an amino acid sequence with a homology of at least 95% to SEQ ID NO: 1.

43. (New) The fusion polypeptide of Claim 19, wherein said tissue factor comprises an amino acid sequence selected from the group consisting of: SEQ ID NO: 1, SEQ ID NO: 2, amino acid positions 11-218 of SEQ ID NO:2, amino acid positions 1-210 of SEQ ID NO:2, and amino acid positions 1-214 of SEQ ID NO:2.

44. (New) A fusion polypeptide, comprising:

    a. a peptide of 3 to 30 amino acids comprising the amino acid sequence RGD, wherein said peptide binds specifically to a $\alpha_v\beta_3$-integrin; and

    b. a tissue factor or a fragment thereof capable of activating blood clotting,

    wherein the amino terminus of said peptide of 3 to 30 amino acids is coupled to the C-terminus of said tissue factor or said fragment thereof.

45. (New) The fusion polypeptide of Claim 44, wherein said fusion polypeptide selectively binds to a tumor vessel endothelial cell expressing a high density of said $\alpha_v\beta_3$-integrin.

46. (New) The fusion polypeptide of Claim 44, wherein said selective binding to a tumor vessel endothelial cell activates said blood clotting.

47. (New) A fusion polypeptide, comprising:

    a. a peptide of 3 to 30 amino acids comprising the amino acid sequence NGR, wherein said peptide binds specifically to a CD13; and

    b. a tissue factor or a fragment thereof capable of activating blood clotting,

    wherein the amino terminus of said peptide of 3 to 30 amino acids is coupled to the C-terminus of said tissue factor or said fragment thereof.

48. (New) The fusion polypeptide of Claim 47, wherein said fusion polypeptide selectively binds to a tumor vessel endothelial cell expressing a high density of said CD13.

49. (New) The fusion polypeptide of Claim 47, wherein said selective binding activates said blood clotting.